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Hazard Evaluation Division, Standard Evaluation Procedure: Directions for Use

Use of Pesticide Programs

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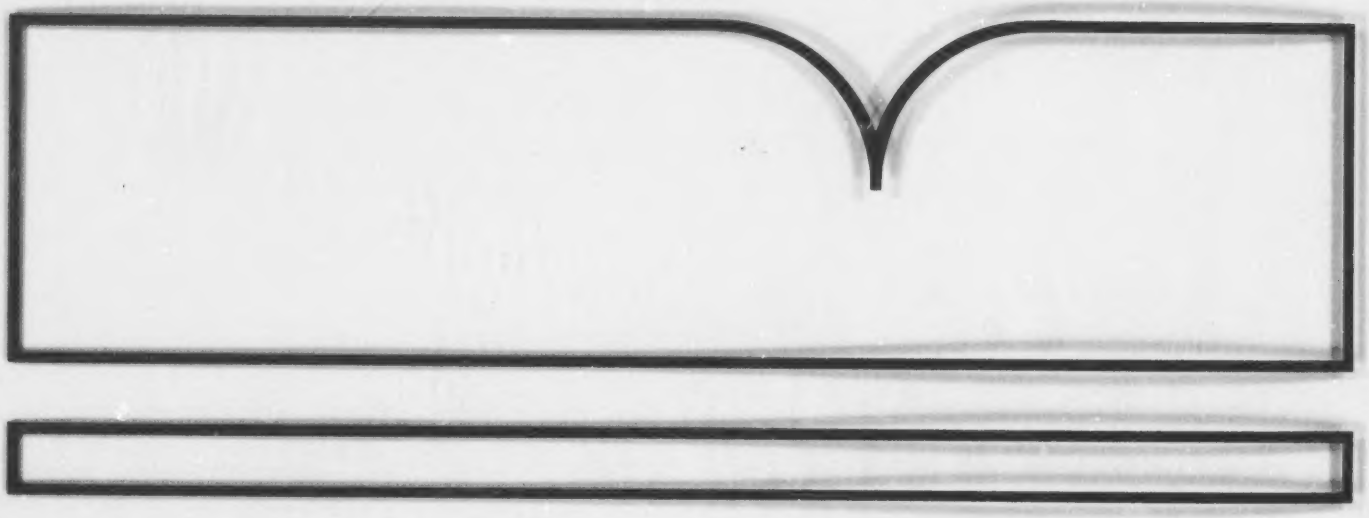

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

DIRECTIONS FOR USE

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Sequential detailed steps for the evaluation of use directions for a chemical pesticide are covered under the following topics: crops, pesticide application, animal treatments, fumigations, aquatic uses, food handling establishments, agricultural premises, and use restrictions. Detailed steps are given such that the reviewer can adequately assess the clarity, conciseness, and accuracy of the pesticide label.

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STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.

Anne L. Barton, Acting Director
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DIRECTIONS FOR USE

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure (SEP) is provided as an aid to the Residue Chemistry Branch (RCB) data reviewers in the evaluation of use directions contained in petitions for tolerance or exemption from tolerance, or its registration submission concerning amended food uses.

B. Background Information

The directions for use form a part of the requirements for the registration, reregistration, or amended registration of pesticides intended for use on agricultural commodities under Sections 408 and 409 of the amended Federal Food, Drug, and Cosmetic Act and the amended Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA amended). Further regulatory support is provided in 40 CFR parts 158.125, 162 and 180.

C. Objective of the Directions For Use

The directions for use provide the user or pesticide applicator with the appropriate methods for the treatment of soils, crops, water, establishments, livestock, and livestock areas with the pesticide. These uses are designed to provide effective, efficacious and safe treatments with pesticides. The use directions are essential to an adequate evaluation of the residue data. As a result such directions must be clear, practical and reflect those uses expected to be effective against the target pest. These data are important in assessing pesticide exposure and risk to the public.

II. THE DATA EVALUATION PROCESS

A. Prepare a Summary

The reviewer is to carefully examine the use directions and provide a summary which is clear, concise, and contains the information necessary to demonstrate the intended use of the pesticide chemical. The information includes the dosage, frequency and timing of application, as well as the mode of delivery. The use directions should show which formulation is to be used, a preharvest interval if necessary, or other limitations as needed. Each of the essential factors of the directions for use are discussed below. The use directions are included in Section B of a petition.

Generally the directions are contained in copies of the labeling and summarized in tabular form. A practical path for the review and evaluation of the use directions is discussed below.

B. Crops

All crops (field and/or orchard) which are to be treated with the pesticide formulation should be clearly identified. The crops listed should be consistent with those for which tolerances have been proposed or exemptions requested. If there are crops listed under the use directions and no tolerance has been proposed on these crops, then the petitioner should be informed that tolerances should be proposed for these crops, or the crops should be withdrawn from consideration. Another option involves a non-food use. If a use is proposed and the petitioner believes that no residues are likely to result in food or feed items, then a tolerance proposal may not be needed. However, residue data must be provided to support this claim. (See SEP entitled, "Specialty Applications: (I) Classification of Seed Treatments and Treatment of Crops Grown for Seed Use Only as Non-Food or Food Uses" for additional information on what constitutes a non-food use).

Conversely, if there are crops for which a tolerance has been proposed and there are no use directions for these crops, then the petitioner should be informed that use directions should be provided for these crops, or the tolerance proposals for these crops should be withdrawn.

The crop groupings represent exceptions to the foregoing discussion (see Section 180.34). A tolerance may be proposed for a collection of related crops (crop group) without use directions for each individual crop in the group. Representative crops from the crop group may be provided as a minimum requirement for data purposes. However, the use directions for all crops in the group must be similar.

C. Pesticide Application

The application of dusts, sprays, and granular formulations are to be expressed in terms of pounds active ingredient per acre. (Occasionally, data from foreign countries are expressed in terms of kilograms per hectare. These units are easily expressed in pounds per acre through the use of readily available conversion factors.) For band or row treatments, the use should indicate if the pounds per acre rate refers to the area treated or to the entire field. For full coverage sprays, for example orchards, the dosage should be expressed as pounds active ingredient per 100 gallons spray solution of runoff. The dosage is expressed in this manner because of the variation in the quantity of active ingredient applied as a result of the variation in the size of the trees. In the case of concentrate orchard sprays, the amount or active ingredient applied per acre should also be related to tree size. Usually, this can be achieved by specifying the same or less active ingredient as the amount which would be applied

using a full coverage spray.

In order to lessen the possibility of excess treatment, some options include information on the labeling which indicate that smaller trees should be treated with less volume of solution and thus less active ingredient per acre. Alternatively, data could be provided to show the maximum likely residues to be expected due to treatment with the most concentrated spray on the smallest, mature fruit-bearing tree in commercial production.

D. Animal Treatments

The uses on animals occur in the form of tags, dusts, dips, pour-ons, and wetting sprays. The concentration of the pesticide in the treatment solution is the primary consideration. The use directions for dips should include instructions for recharging and maintaining a constant solution strength in the dip tank and for the disposal of spent dip solutions. Factors which may affect the deposition of residues on animals should be included in the use directions. Some of the factors include the maximum number of treatments; amount of time that the animal is to be held in the dip tank; the delivery rate of sprays; and the amount of solution to be applied per animal for spot or other specialized treatments.

For the application of pesticides by automatic devices, for example, photoelectric or treadle actuated sprays, or back-rubbers, the use directions should include discussions on the recharging and placement of devices so that the degree of exposure of the animals may be estimated.

E. Fumigation

Dosages may be expressed in terms of weight of fumigant per volume of storage space (pounds active ingredient per 100 cubic feet) or weight of fumigant per unit weight of commodity treated (pounds active ingredient per 1000 pounds grain) or weight of fumigant per unit areas and depth of preplant field treatment. Other factors should also be noted. Such factors are time of exposure; temperature; pressure; geometry and airtightness of containers; and aeration procedures (including time of aeration).

F. Aquatic Uses

Aquatic uses entail the application of a pesticide to flowing water, impounded water, irrigation ditch banks, dry beds of water conveyance systems, and other aquatic sites.

The mode of application varies and depends on the intended effect of the pesticide. Herbicides for deep growing submersed weeds may require deposition of slow release granules on the bottom near the root zone. For this type of treatment the dosage would be expressed in terms of pounds active ingredient per surface acre. The use of a water-soluble herbicide which acts by

direct absorption into the target plant is dependent upon maintaining a certain concentration in the water, and the dosage should be expressed in terms of parts per million in water. The use directions should relate the dosage per surface acre to average pond depth.

Specialized equipment may be required for some aquatic herbicide applications. As a result, a detailed description of the equipment and principles involved in the treatment should be included. For example, metered pumping of invert emulsions to the bottom of lakes through weighted hoses may be used. A proposed use of timed release capsules will require information on how the encapsulated material is placed and the mechanisms of the release.

Often some limitations on the minimum distance from a potable water or irrigation intake pipe are included. Such limitations are needed whenever unacceptable levels of a pesticide chemical occur in water at the intake pipe.

In order to avoid losses of desirable species through oxygen depletion, it is sometimes necessary to treat at intervals only portions of ponds with heavy infestations. The label should state what proportions of a pond should be treated per application and the required interval between treatments. If treatments are intended only for pond margins, as opposed to overall broadcast treatment, then it should be so indicated.

Ditch bank treatments are usually made by boom sprayers from trucks. For adequate coverage there is an unavoidable overlap with some direct addition to the water as well as runoff contamination. The label should clearly indicate how such treatments are to be made with minimum contribution of herbicide to water. A prohibition may be required against cross-ditch spraying.

G. Food Handling Establishments

The potential exists for the contamination of foods due to pesticide treatments of areas where food is prepared or processed. Therefore, the applicator must have clear use directions in order to minimize the contamination of foods.

The directions for use should include the type of establishment that may be treated; the dilution instructions for preparing the working solutions; the spray concentration; the type of application equipment; the mode of application (e.g., directed spray to crevices, baseboards, space spray, etc.); dosage limitations including cubic and square foot limitations; frequency of treatment; time of treatment (e.g., after-hours in restaurants). Other information which should be provided, where necessary, are as follows: sanitation procedures; removal of food; covering dishes and utensils; and cleanup procedures before food preparation, processing, or serving resumes.

H. Agricultural Premises

Agricultural premise uses include distribution of granular insecticides to feed lots; fogging of dairy barns; installation of impregnated strips or cords in animal barns; and applications of sugar-based bait sprays to walls, stanchions, and other surfaces of barns. The use directions should be sufficiently detailed to permit an evaluation of the potential for residues on milking equipment, exposure to feeds, drinking and feed troughs, or in meat, milk, and eggs of livestock housed on treated premises. The use directions should state what areas are to be treated, the frequency of treatment, whether animals must be removed at time of treatment, and any other pertinent information. Dosage for fogging treatments should be expressed in terms of number of fogging devices per unit volume; sprays in terms of concentration of active ingredient in the solution applied; and, feed lot applications in terms of weight of active ingredient per unit area.

I. Use Restrictions

In addition to the directions for use of the pesticide, there are often restrictions placed on the use of the pesticide. Such restrictions should be clearly written and practical. The following is a summary of the use restrictions commonly noted and the information needed to adequately support such restrictions.

- The maximum number of applications permitted during a growing season should be indicated. Also, the timing of the applications should be noted as well as the intervals permitted between treatment.

- The interval between the last application and harvested should be indicated. This interval is commonly referred to as the pre-harvest interval, or PHI, and expressed in days. For animal treatments, the interval between the last treatment and slaughter is commonly referred to as the pre-slaughter interval, or PSI, and usually expressed in days.

  For crops the timing of the application may be tied to a stage of crop growth. For example, with cotton the statement "not after first bolls open" is used. Again, information on the minimum interval from the treatment stage to harvest is needed.

Impractical or unrealistic use restrictions should be avoided. Restrictions on the food or feed use of plant parts are practical only when: (1) the item remains under the direct control of the grower; (2) the item is not of significant economic importance as a feed item; and, (3) the U.S. customary practice

is not to use the item as a feed. For example, a restriction on the feed use of soybean straw is practical because the plant refuse remains under the control of the grower, the item is not of significant economic importance as a feed item, and the percentage of U.S. soybean acreage fed is very low.

Also a restriction in the form of a PHI would be practical for pasture grass. Conversely, restrictions on the feed use of corn forage or fodder would be impractical since these are major livestock feed items. While corn forage and fodder are under the control of the grower, the high economic value of the feed items and the overwhelming practice of growers to feed these items make the restriction impractical.

- The use restrictions should be as specific as possible. For example, a restriction such as "Do not use after lay-by" is indefinite because the "lay-by time" may vary considerably for a given crop. Indefinite terms such is "Do not use on animals being finished for slaughter" should not be accepted. Instead, a specific withdrawal period should be requested of the petitioner.

- Where use in food handling establishments is proposed, specific use directions to minimize residue transfer are needed. Explicit warnings such as "Cover food utensils" is most useful. However, a general statement such as "Avoid contamination of food" is less useful and therefore of limited effectiveness.

III. REVIEWER AIDS

Cultural practices files for agricultural crops are available in the Residue Chemistry Branch file area. These files are invaluable in providing information on agricultural crops, their byproducts, and market information on the distribution of the crops into economic channels. These files should be consulted when questions arise concerning agricultural crops and other pesticide uses.

Other sources of up-to-date information on cultural practices for plants and animals include:

- USDA Publication, "Information Contacts."

- USDA Telephone Directory, Science & Education Staff, pp. 106-109, Spring 1984 (update annually).

- USDA Handbook Number 305, "1984-85

Directory of Professional Workers in State Agricultural Experiment Stations and other cooperating State Institutions" (updated annually).

Miscellaneous reference books are available throughout the branch on many crops.